This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical, and it is presented here exactly as submitted.

Portions of this document (pages 2-17) have been claimed confidential. This document is releasable to persons who submit a signed "Affirmation of Non-Multinational Status" form.

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BASF RESPONSE TO THE EPA PRELIMINARY RISK ASSESSMENT FOR VINCLOZOLIN

MARCH 16, 2000

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BASF RESPONSE TO THE EPA PRELIMINARY RISK ASSESSMENT FOR VINCLOZOLIN

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BASF RESPONSE TO VINCLOZOLIN PRELIMINARY RISK ASSESSMENT ACUTE DIETARY RISK

The Agency conducted a probabilistic/Monte Carlo type of acute dietary risk assessment using an aPAD (which includes retention of the additional 10X FQPA safety factor) of 0.006 mg/kg/day based on an *in utero* developmental effect. The risk assessment was conducted including anticipated residue information derived from residue distributions from residue field trials and with consideration of percent market share. Market share information included in the assessment was developed by the Agency and transmitted in a document entitled "***Quantitative Useage Analysis for Vinclozolin***" dated November 3, 1999.

The Agency has characterized this acute risk assessment as ***"somewhat refined"*** in recognition of the fact that use of additional exposure information (monitoring data) would further refine the risk assessment. The Agency has suggested that the available monitoring data is insufficient for inclusion in risk assessments because the data is generated using methodology which determines parent residue only and does not account for vinclozolin metabolites containing the 3,5-dichloroaniline moiety which might be of concern. BASF believes that this data can be used provided a conversion factor is applied which relates parent residues to total residues. Based on its analysis of available metabolism data, BASF has suggested a conversion factor of 1.5 be applied. The Agency has rejected this assessment, suggesting that the available data is too variable to support the factor. Included in another section of this response to the Agency's Preliminary Risk Assessment is a statistical treatment of the data which shows that there is a high degree of correlation between parent and total residues in the available metabolism data which supports a conversion factor of from 1.3 to 1.7.

In it's risk assessment, the Agency determined that the following percents of the aPAD are consumed at the 99^{th}, 99.5^{th} and 99.9^{th} percentiles respectively: 35, 57 and 170 when all currently registered uses and newly proposed uses (succulent beans and canola) are considered. The primary risk driver in this analysis according to the Agency's assessment is imported wine. Specific issues on the calculation of anticipated residues for imported wine are dealt with in another section of this response.

In its Federal Register publications establishing tolerances and in its reregistration eligibility determinations the Agency has established a consistent philosophy regarding regulation concerning acute dietary risk. Recognizing that unrefined risk assessments incorporate a high degree of conservatism, the Agency has consistently regulated at the 95th percentile when there are no refinements to the residue input data. When the data are highly refined the Agency consistently regulates at the 99.9^{th} percentile, presuming that there is a much higher degree of confidence that the residues reflect real world exposure and that the degree of conservatism in the assumptions is reduced. BASF continues to have reservations concerning regulation at the 99.9^{th} percentile in general. Most of these concerns have been expressed by the Implementation Working Group's

responses to the Agency on this issue. However, BASF does understand the Agency's basic idea that the more refined the data, the less conservative the exposure assumptions, the more realistic and precise the assessment. As the assessments become more precise there is less conservative bias caused by the assumptions and therefore it is reasonable to regulate at a higher percentile of the population.

BASF believes that the Agency should continue to identify where it should regulate based on its analysis of the individual assessment conducted. In this case it is clear that the refinement of the analysis is neither unrefined nor highly refined, therefore it would be inappropriate, based on the Agency's previous decisions, to regulate at either the 99th or the 99.9th percentile. **Given the degree of refinement, BASF believes that regulation at the 99th percentile should be adequate to satisfy the FQPA criteria of reasonable certainty of no harm.**

95th ?.

RESPONSE TO VINCLOZOLIN PRELIMINARY RISK ASSESSMENT
ONCOGENIC RISK ASSESSMENT OF VINCLOZOLIN

The Agency has assessed oncogenic risk for exposure to vinclozolin in two distinct ways. The first and more appropriate is the use of a Margin of Exposure approach based on the thorough understanding of the mechanism of Leydig Cell tumor generation. The second approach is linear dose response model using Q* to calculate excess oncogenic risk.

The mechanism of Leydig Cell tumor production in the rat is well understood. The Agency presented the information to the Office of Pesticide Program's Scientific Advisory Panel in January of 1997. After a thorough review of this information the Panel concluded relative to oncogenicity, ***"the classification of vinclozolin using the new guidelines would be not likely to be a carcinogenic hazard to humans".*** They also concluded that ***"the appropriate method of risk quantification is on a non-linear model, MOE approach based on a NOEL for non-neoplastic anti-androgenic effects."***

In October, 1997 the Agency established a time limited tolerance in succulent beans based on the MOE approach recommended by the SAP. ***"Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), EPA has classified vinclozolin as a Group C chemical - possible human carcinogen. The Agency Cancer Peer Review Committee (CPRC) chose a non-linear approach [MOE] based on a NOEL of 4.9 mg/kg/day for hormone-related effects [decreased epididymal weight at 30 mg/kg/day] in the 2-generation oral rat reproductive toxicity study to quantify human risk. The MOE approach was chosen because the remaining tumors [Leydig cell] were benign at dose levels which were not considered to be excessive."***

Using the MOE approach and a "somewhat refined" exposure assessment for food, the MOE for all currently registered and proposed uses as expressed in the Agency's Preliminary Risk Assessment, is >100,000. The Agency has characterized its dietary risk assessment as ***"somewhat refined"*** in recognition of the fact that use of additional exposure information (monitoring data) would further refine the risk assessment. The Agency has suggested that the available monitoring data is insufficient for inclusion in risk assessments because the data is generated using methodology which determines parent residue only and does not account for vinclozolin metabolites containing the 3,5-dichloroaniline moiety which might be of concern. BASF believes that this data can be used provided a conversion factor is applied which relates parent residues to total residues. Based on its analysis of available metabolism data, BASF has suggested a conversion factor of 1.5 be applied. The Agency has rejected this assessment, suggesting that the available data is too variable to support the factor. Included in another section of this response to the Agency's Preliminary Risk Assessment is a statistical treatment of the data which shows that there is a high

degree of correlation between parent and total residues in the available metabolism data which supports a conversion factor of from 1.3 to 1.7. **Use of the available monitoring data and the proposed conversion factor leads one to a calculated dietary MOE approaching 1,000,000.**

Using the Agency's conservative "somewhat refined" dietary exposure calculations and the extremely conservative values for water exposure contained in the Agency's Preliminary Risk Assessment, the MOE considering food and water is >80,000.

BASF believes the water exposure numbers are extremely conservative since the models used to calculate the values themselves are conservative and the assumptions used to run the models are also very conservative. BASF's analysis of water exposure is found in another section of this response.

BASF believes that the MOE for all current and proposed uses of vinclozolin is at least >80,000. This extremely high margin of safety should be more than adequate to satisfy the FQPA criteria of reasonable certainty of no harm.

BASF RESPONSE TO VINCLOZOLIN PRELIMINARY RISK ASSESSMENT DIETARY EXPOSURE/IMPORTED WINE

BASF believes that there is no unreasonable risk to the consumption of wine treated with vinclozolin when the appropriate regulatory criteria, described previously in this response, are applied. Since it is not yet clear whether those criteria will in fact be used in the final risk assessment, BASF believes there is additional information which will allow the Agency to refine its dietary exposure assessments as they apply to the use of vinclozolin.

For both acute and chronic exposure BASF believes that available monitoring data can be used when an appropriate conversion factor is applied to that data. This issue is addressed in another section of this response.

BASF believes that a concentration factor of 0.44 should be applied to the residue data input file when exposure is calculated. BASF has submitted a grape processing report (MRID 40019001) which has been reviewed by the Agency. In that report, grapes from 12 trials were juiced and the residues in the juice compared to the residues in the whole fruit. The residue method was a total method which read vinclozolin and its 3,5-dichloroaniline metabolites as the 3,5-dichloroaniline. The concentration factors (residue in juice divided by residue in whole fruit) calculated ranged from 0.25 to 0.72 and averaged 0.44. BASF believes this concentration factor is conservative since it does not take into account any further degradation of vinclozolin and its metabolites which would be expected during the fermentation and following steps in wine production.

The Agency has indicated in its exposure assessments that the market share information for imported commodities is extremely conservative and could be refined if additional data were supplied. In the case of imported wine the Agency has indicated that additional data concerning use of vinclozolin in Europe and Chile would be of value. While BASF has a registration for the use of vinclozolin on wine grapes in Chile, BASF has not sold or distributed any product for this use in Chile for the last 3 years. Information concerning the use of vinclozolin in grapes in Europe is found in the Table following this page. The data show that vinclozolin is used on less than 1% of the fungicide treatment acres in Europe. This data is a compilation of data generated by independent market research panels and purchased by BASF. The data represent all grapes, not just wine grapes, however wine grapes represent >95% of European production.

VINCLOZOLIN MARKET SHARE
GRAPES/EUROPE

		Vinclozolin treated (HA)	Total [1] Treated (HA)	% total treated
East Europe	1997	20410	1809450	1.13
	1998	15780	1646150	0.96
	1999	15680	1827000	0.86
West Europe	1997	139390	31296910	0.45
	1998	70510	28277300	0.25
	1999	101060	28136020	0.36
Total	1997	121470	33106360	0.37
	1998	86290	29923450	0.29
	1999	116740	29963020	0.39

[1]These are treatment hectares. Each time a hectare is treated it counts as a treatment hectare. For reference, there are approximately 3,000,000 hectares grown to grapes throughout East and West Europe.

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REPORT TITLE

Individual Determination of Vinclozolin and its Metabolites In Grapes

DATA REQUIREMENT
EPA Guideline 171-4

AUTHOR

Laura Sears
BASF Corporation

Report Date
March 16, 2000

This report consist of 17 pages.

REPORT NUMBER:

BASF REG.DOC. Number 2000/5082

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BASF RESPONSE TO VINCLOZOLIN PRELIMINARY RISK ASSESSMENT WATER EXPOSURE TO VINCLOZOLIN

The Agency has calculated exposure to vinclozolin from water in its Preliminary Risk Assessment. Two exposure models were use; SCIGROW for the estimation of ground water concentrations and the Index Reservoir Model for estimation of surface water exposure. BASF believes that there is no unreasonable risk to the consumption of water associated with the use of vinclozolin when the appropriate regulatory criteria, described previously in this response, are applied. Since it is not yet clear whether those criteria will in fact be used in the final risk assessment, BASF believes there is additional information which will allow the Agency to refine its water exposure assessments for vinclozolin as they apply to vinclozolin use.

BASF believes both models represent overly conservative estimations of exposure to vinclozolin in water.

SCIGROW: In addition to the very conservative assumptions used to build the model the assumptions used concerning use rates used to run the model cause an overestimation. The Agency has assumed that all acres of each crop are treated at the maximum labeled rate. In fact, the Agency has reliable data to show that this is not the case. Market share information is included in the Agency's Preliminary Risk Assessment. This information was developed by the Agency and transmitted in a document entitled ***"Quantitative Useage Analysis for Vinclozolin"*** dated November 3, 1999. That analysis shows that vinclozolin, in general, treats a small percentage of the total area of any individual crop and when used, vinclozolin is used at frequencies and rates much lower than the maximum the label would allow.

The SCIGROW assessment done was conducted on the use, which the Agency determined was the most conservative (i.e. the highest use rate and the highest number of applications). In this case, the use chosen was the onion use. Here the label allows a maximum of five applications at 1 pound active ingredient per acre. The data contained in the Useage Analysis shows that the average use pattern (when vinclozolin is used at all) is two applications at 0.5 pounds active ingredient per acre. While it may be appropriate to consider the most conservative exposure scenario when assessing chronic risk when there is no data concerning realistic average exposure, it is inappropriate to do so when there is reliable data available. BASF has used SCIGROW to calculate exposure from ground water using the known average use pattern and finds that number to be 0.11 ppb (micrograms/liter). Even this assessment is a vast overestimation of exposure as the average percentage of the total onion acreage treated with vinclozolin is approximately 1%.

INDEX RESERVOIR: In addition to the very conservative assumptions used to build the model the assumptions used concerning use rates used to run the model cause an overestimation. The Agency has assumed that all acres of each crop are treated at the

maximum labeled rate. In fact, the Agency has reliable data to show that this is not the case. Market share information is included in the Agency's Preliminary Risk Assessment. This information was developed by the Agency and transmitted in a document entitled "***Quantitative Useage Analysis for Vinclozolin***" dated November 3, 1999. That analysis shows that vinclozolin, in general, treats a small percentage of the total area of any individual crop and when used, vinclozolin is used at frequencies and rates much lower than the maximum the label would allow.

The Index Reservoir assessment done was conducted on the use, which the Agency determined was the most conservative (i.e. the highest use rate and the highest number of applications). In this case, the use chosen was the onion use. Here the label allows a maximum of five applications at 1 pound active ingredient per acre. The data contained in the Useage Analysis shows that the average use pattern (when vinclozolin is used at all) is two applications at 0.5 pounds active ingredient per acre. While it may be appropriate to consider the most conservative exposure scenario when assessing chronic risk when there is no data concerning realistic average exposure, it is inappropriate to do so when there is reliable data available. BASF has little experience in using the Index Reservoir model but has used it to calculate exposure from surface water using the known average use pattern and finds that number to be 0.04 ppb (micrograms/liter). Even this assessment is a vast overestimation of exposure as the average percentage of the total onion acreage treated with vinclozolin is approximately 1%.

In addition, BASF notes that as input to the model, a load equivalent to 16% the use is applied to the reservoir as an estimation of drift load from air application. This appears to be the number that drives the subsequent exposure value. Based on its understanding of the Spray Drift Task Force data in the hands of the Agency, BASF believes this theoretical load could only occur under worst case conditions and only if the reservoir was within direct proximity (100 feet or less) of the treated field. This kind of an assumption can only be justified if one is trying to account for accidents in application. Air applicators are acutely aware of their responsibilities to minimize drift. To contemplate air application under severe application conditions within a very short distance from a reservoir as a realistic worst case exposure simply defies logic and common sense.

BASF RESPONSE TO VINCLOZOLIN PRELIMINARY RISK ASSESSMENT WATER EXPOSURE TO 3,5-DICHLOROANILINE

The Agency has calculated exposure to 3,5-dichloroaniline (DCA) from water in its Preliminary Risk Assessment. Two exposure models were use; SCIGROW for the estimation of ground water concentrations and the Index Reservoir Model for estimation of surface water exposure. BASF believes there is additional information which will allow the Agency to refine its water exposure assessments for vinclozolin as they apply to vinclozolin use. BASF believes both models represent overly conservative estimations of exposure to vinclozolin in water.

SCIGROW: In addition to the very conservative assumptions used to build the model the assumptions used concerning use rates used to run the model cause an overestimation. The Agency has assumed that all acres of each crop are treated at the maximum labeled rate. In fact, the Agency has reliable data to show that this is not the case. Market share information is included in the Agency's Preliminary Risk Assessment. This information was developed by the Agency and transmitted in a document entitled ***"Quantitative Useage Analysis for Vinclozolin"*** dated November 3, 1999. That analysis shows that vinclozolin, in general, treats a small percentage of the total area of any individual crop and when used, vinclozolin is used at frequencies and rates much lower than the maximum the label would allow. In addition, it appears that the Agency has assumed that each molecule of vinclozolin is converted to a molecule of DCA.

The SCIGROW assessment done was conducted on the use, which the Agency determined was the most conservative (i.e. the highest use rate and the highest number of applications). In this case, the use chosen was the onion use. Here the label allows a maximum of five applications at 1 pound active ingredient per acre. The data contained in the Useage Analysis shows that the average use pattern (when vinclozolin is used at all) is two applications at 0.5 pounds active ingredient per acre. While it may be appropriate to consider the most conservative exposure scenario when assessing chronic risk when there is no data concerning realistic average exposure, it is inappropriate to do so when there is reliable data available. BASF has reviewed the environmental fate data base for vinclozolin and can find no case where the conversion of vinclozolin to DCA exceeds 10%. BASF has used SCIGROW to calculate exposure from ground water using the known average use pattern and a 10% conversion factor for DCA formation from vinclozolin and finds that number to be 0.26 ppb (micrograms/liter). Even this assessment is a vast overestimation of exposure as the average percentage of the total onion acreage treated with vinclozolin is approximately 1%.

INDEX RESERVOIR: In addition to the very conservative assumptions used to build the model the assumptions used concerning use rates used to run the model cause an overestimation. The Agency has assumed that all acres of each crop are treated at the maximum labeled rate. In fact, the Agency has reliable data to show that this is not the

case. Market share information is included in the Agency's Preliminary Risk Assessment. This information was developed by the Agency and transmitted in a document entitled "***Quantitative Useage Analysis for Vinclozolin***" dated November 3, 1999. That analysis shows that vinclozolin, in general, treats a small percentage of the total area of any individual crop and when used, vinclozolin is used at frequencies and rates much lower than the maximum the label would allow. In addition, it appears that the Agency has assumed that each molecule of vinclozolin is converted to a molecule of DCA.

The Index Reservoir assessment done was conducted on the use, which the Agency determined was the most conservative (i.e. the highest use rate and the highest number of applications). In this case, the use chosen was the onion use. Here the label allows a maximum of five applications at 1 pound active ingredient per acre. The data contained in the Useage Analysis shows that the average use pattern (when vinclozolin is used at all) is two applications at 0.5 pounds active ingredient per acre. While it may be appropriate to consider the most conservative exposure scenario when assessing chronic risk when there is no data concerning realistic average exposure, it is inappropriate to do so when there is reliable data available. BASF has reviewed the environmental fate data base for vinclozolin and can find no case where the conversion of vinclozolin to DCA exceeds 10%. BASF has little experience in using the Index Reservoir model but has used it to calculate exposure from surface water using the known average use pattern and 10% conversion of vinclozolin to DCA and finds that number to be 0.22 ppb (micrograms/liter). Even this assessment is a vast overestimation of exposure as the average percentage of the total onion acreage treated with vinclozolin is approximately 1%.

In addition, BASF notes that as input to the model, a load equivalent to 16% the use is applied to the reservoir as an estimation of drift load from air application. This appears to be the number that drives the subsequent exposure value. Based on its understanding of the Spray Drift Task Force data in the hands of the Agency, BASF believes this theoretical load could only occur under worst case conditions and only if the reservoir was within direct proximity (100 feet or less) of the treated field. This kind of an assumption can only be justified if one is trying to account for accidents in application. Air applicators are acutely aware of their responsibilities to minimize drift. To contemplate air application under severe application conditions within a very short distance from a reservoir as a realistic worst case exposure simply defies logic and common sense.

BASF RESPONSE TO VINCLOZOLIN PRELIMINARY RISK ASSESSMENT AGGREGATE RISK/NON-OCCUPATIONAL EXPOSURE

GOLF COURSE USE: The Agency has indicated that adequate margins of exposure exist for this use.

SOD FARM USE: The Agency has indicated a level of concern for children contacting newly sodded lawns treated with vinclozolin as part of disease management on the sod farm. The Agency has indicated that this is a reentry problem and that an adequate margin of safety can be obtained if a 22 day time period elapsed between treatment and removing the sod from the farm. BASF's comments on reentry can be found in another section of this document. In short, BASF believes that the data when properly treated, would support a shorter time period between treatment and removal from the sod farm.

Regardless of what is finally determined to be the proper reentry interval for children BASF believes that this time period can be established via a label amendment.

BASF RESPONSE TO VINCLOZOLIN PRELIMINARY RISK ASSESSMENT WORKER EXPOSURE

MIXERS, LOADERS AND APPLICATORS: BASF disributes vinclozolin in the Agricultural market place as a 50% extruded granule (EG) formulation in water soluble packaging. As of January 30, 2000 BASF will no longer manufacture or distribute any other formulation in the ornamental market place. BASF has abstracted all the current uses from the Preliminary Risk Assessment and placed them in two tables.

TABLE I shows the mixer/loader exposures and MOEs. The use of WSB packaging puts vinclozolin into the "Engineering Controls" scenario: long pants; long-sleeved shirt; socks; shoes; no gloves; no respirator. All combined dermal and inhalation MOE approached or exceeded 5,000. Note that the current label also requires personal protective equipment (PPE) exceeding the evaluated scenario:

--Coveralls over long pants and long-sleeved shirt.
--Waterproof gloves.
--Protective eyewear.
--Chemical-resistant apron.
--Dust/mist respirator.

Under this evaluation, the additional PPE need not be required.

TABLE II shows the application exposures and MOEs, along with the PPE scenarios. All combined dermal and inhalation MOE exceeded 100, ranging from 115 to >1,100.

--Baseline=Long pants; long-sleeve shirt; socks; shoes; no gloves; no respirator.
--Minimum PPE=Long pants; long-sleeve shirt; socks; shoes; waterproof gloves; no respirator.
--Engineering Controls--Aerial=Closed cockpit; long pants; long-sleeve shirt; socks; shoes; no gloves; no respirator.
--Engineering Controls--Airblast=Closed cabs; long pants; long-sleeve shirt; socks; shoes; waterproof gloves; no respirator.

Again, the label requires PPE in excess of that required to achieve acceptable MOE for most scenarios.

We note that the default maximum rates of use (Lb AI/acre) and acres treated per day are substantially greater than the actual usage. Since the MOE under the screening level assumptions were not at a level of concern, we did not refine the assessment at this time. TABLES I and II are presented without further comment.

TABLE I

Mixer/loader margins of exposure: Vinclozolin extruded granules in water soluble bags.

Filename Vincloz MLA 03-06-00.xls

3.0 NOAEL, mg/kg BW/day, oral
25.2% Percutaneous absorption Duration: Acute/short/intermediate-term.
60 kg BW, standard female bodyweight

			mg/Lb AI		MOEs:			
	Lb AI/A	Acres/day	Dermal	Inhalation	Dermal	Inhalation	Combined	Scenario
Mix/Load--Aerial Application and Chemigation								
Canola	0.45	350	0.000168	0.000034	26,995	33,613	14,971	Engineering Controls
Snapbeans	0.50	350	0.000168	0.000034	24,295	30,252	13,474	Engineering Controls
Lettuce/Onions	1.00	350	0.000168	0.000034	12,148	15,126	6,737	Engineering Controls
Turf--Sod farm	1.35	350	0.000168	0.000034	8,998	11,204	4,990	Engineering Controls
Ornamentals	1.30	350	0.000168	0.000034	9,344	11,635	5,182	Engineering Controls
Mix/Load--Airblast								
Raspberry/Kiwi	1.00	40	0.000168	0.000034	106,293	132,353	58,950	Engineering Controls
Ornamentals	1.30	40	0.000168	0.000034	81,763	101,810	45,346	Engineering Controls
Mix/Load--Ground Boom								
Canola	0.45	80	0.000168	0.000034	118,103	147,059	65,500	Engineering Controls
Snapbeans	0.50	80	0.000168	0.000034	106,293	132,353	58,950	Engineering Controls
Lettuce/Onions	1.00	80	0.000168	0.000034	53,146	66,176	29,475	Engineering Controls
Turf--Sod farm	1.35	80	0.000168	0.000034	39,368	49,020	21,833	Engineering Controls
Ornamentals	1.30	80	0.000168	0.000034	40,882	50,905	22,673	Engineering Controls
Mix/Load--High Pressure Handwands								
Ornamentals	1.30	5	0.000168	0.000034	654,108	814,480	362,769	Engineering Controls
Mix/Load--Low Pressure/High Volume Turfgun								
Turf--Golf Course	1.35	5	0.000168	0.000034	629,882	784,314	349,333	Engineering Controls
Mix/Load--Dipping								
Cut Flowers et al.	1.50	1	0.000168	0.000034	2,834,467	3.5E+06	1,571,997	Engineering Controls

Engineering Controls=Water Soluble Bag; long pants; long-sleeve shirt; socks; shoes; no gloves; no respirator.

NOTE: The "Dipping" scenario has been normalized to Lb AI/day--The 1-acre value is the normalized multiplier.

TABLE II

Applicator margins of exposure: Vinclozolin extruded granules in water soluble bags.

Filename Vincloz MLA 03-06-00.xls

3.0 NOAEL, mg/kg BW/day, oral
25.2% Percutaneous absorption Duration: Acute/short/intermediate-term.
60 kg BW, standard female bodyweight

			mg/Lb AI		MOEs:			
	Lb AI/A	Acres/day	Dermal	Inhalation	Dermal	Inhalation	Combined	Scenario
Aerial Application								
Canola	0.45	350	0.005	0.000068	907	16,807	861	Engineering Controls
	0.50	350	0.005	0.000068	816	15,126	775	Engineering Controls
Lettuce/Onions	1.00	350	0.005	0.000068	408	7,563	387	Engineering Controls
Turf--Sod farm	1.35	350	0.005	0.000068	302	5,602	287	Engineering Controls
Ornamentals	1.30	350	0.005	0.000068	314	5,818	298	Engineering Controls
Airblast Application								
Raspberry/Kiwi	1.00	40	0.019	0.00045	940	10,000	859	Engineering Controls
Ornamentals	1.30	40	0.019	0.00045	723	7,692	661	Engineering Controls
Ground Boom Application								
Canola	0.45	80	0.014	0.00074	1,417	6,757	1,172	Baseline
Snapbeans	0.50	80	0.014	0.00074	1,276	6,081	1,054	Baseline
Lettuce/Onions	1.00	80	0.014	0.00074	638	3,041	527	Baseline
Turf--Sod farm	1.35	80	0.014	0.00074	472	2,252	391	Baseline
Ornamentals	1.30	80	0.014	0.00074	491	2,339	406	Baseline
High Pressure Handwand Application								
Ornamentals	1.30	5	0.64	0.079	172	351	115	Min. PPE. No Respirator.
Low Pressure/High Volume Turfgun Application								
Turf--Golf Course	1.35	5	0.77	0.0014	137	19,048	136	Baseline
Dipping								
Cut Flowers et al.	1.50	1	No Data					
Flagging								
Canola	0.45	350	0.011	0.00035	412	3,265	366	Baseline
Snapbeans	0.50	350	0.011	0.00035	371	2,939	329	Baseline
Lettuce/Onions	1.00	350	0.011	0.00035	186	1,469	165	Baseline
Turf--Sod farm	1.35	350	0.011	0.00035	137	1,088	122	Baseline
Ornamentals	1.30	350	0.011	0.00035	143	1,130	127	Baseline

Baseline=Long pants; long-sleeve shirt; socks; shoes; no gloves; no respirator.
Minimum PPE=Long pants; long-sleeve shirt; socks; shoes; waterproof gloves; no respirator.
Engineering Controls--Aerial=Long pants; long-sleeve shirt; socks; shoes; no gloves; no respirator.
Engineering Controls--Airblast=Long pants; long-sleeve shirt; socks; shoes; waterproof gloves; no respirator.

BASF RESPONSE TO VINCLOZOLIN PRELIMINARY RISK ASSESSMENT WORKER RENTRY

In the US Environmental Protection Agency (EPA, Agency) draft reregistration eligibility document for vinclozolin dated 15 July 1997, the EPA calculated dislodgeable foliar residue (DFR, $\mu g/cm^2$) decline curves with an exponential decay model as follows:

$$C_{envir(t)} = C_{envir(0)} e^{PAI(t) * M}$$

In 3 previous reports we demonstrated that the Agency "Best Fit" dissipation curves simply did not fit the data:

> VINCLOZOLIN 50 DF: REEVALUATION OF REENTRY EXPOSURE AND MARGINS OF EXPOSURE IN STRAWBERRIES, 13 OCTOBER 1997. D. G. Baugher, Ph.D., Orius Associates Inc. Report No. 97016/VIN, 67 pages. MRID Number 44409401.
>
> VINCLOZOLIN 50 DF: REEVALUATION OF REENTRY EXPOSURE AND MARGINS OF EXPOSURE IN PEACHES, 20 OCTOBER 1997. D. G. Baugher, Ph.D., Orius Associates Inc. Report No. 97019/VIN, 26 pages. MRID Number 44409402.
>
> VINCLOZOLIN 50 DF: REEVALUATION OF REENTRY EXPOSURE AND MARGINS OF EXPOSURE IN TURF, 15 OCTOBER 1997. D. G. Baugher, Ph.D., Orius Associates Inc. Report No. 97017/VIN, 24 pages. MRID Number 44409403.

We have re-examined the Orius Associates (now EXP Corporation) curve-fitting and would make only minor changes that would have little impact on the predicted DFRs. This curve fitting describes the actual data much better than the equation derived by the Agency.

The Agency has used its original approach in the current document at pages 57 through 60:

> The Revised Occupational and Residential Exposure Aspects of the HED Chapter of the Reregistration Eligibility Decision Document (RED) for Vinclozolin, Case #816411, PC Code 113201, DP barcode D260678. 8 February 2000. Jeffery L. Dawson through Whang Phang to William Hazel. 264 pages.

The Agency-predicted DFRs do not fit the data. In the following TABLE we show the days after treatment and the Agency-predicted DFRs as a percent of the underlying observed mean DFRs.

In the time-periods of interest, the predicted DFR are approximately 2X to 13X the observed residues. Calculated exposures would therefore be 2X to 13X greater than exposures based on the observed mean DFRs. Calculated margins of exposure would be one-half to one-thirteenth those based on observed mean DFRs.

TABLE I

EPA-predicted DFR as % of observed:

Day	Turf	Strawberry	Peach
0	100%	100%	100%
1	62%	99%	124%
2	104%	98%	214%
3	48%	127%	297%
5		160%	
7	295%	205%	400%
10	327%	266%	545%
14	224%	177%	930%
21	385%	376%	1307%
28	308%	1337%	1311%
35	116%	532%	1432%
42		420%	1006%
49		381%	471%
56		214%	441%
63		426%	138%

Reentry Intervals should be recalculated using a regression equation which better fits the data.

BASF notes that the Agency has used a dermal adsorption factor of 25% for all dermal toxicity calculations. BASF believes that this is an overestimation of dermal adsorption. BASF also believes that the dermal adsorption factor used in these calculations should be modified based on the study submitted (MRID 42483103) which compares penetration of rat and human skin. Using the most conservative value dermal adsorption is reduced from 25% to 6%. A short description of that data follows this page.

BASF Aktiengesellschaft
Product Safety
Regulations, Toxicology and Ecology

Reg.Doc.# BASF: 2000/5065

Date: 07 March 2000

STATEMENT:

DERMAL PENETRATION OF

VINCLOZOLIN

STATEMENT:
DERMAL PENETRATION OF VINCLOZOLIN

Summary

The dermal penetration of vinclozolin has been investigated *in vivo* using rats and a comparison of penetration between rats and humans was studied *in vitro*. Data from both studies should be considered to determine the dermal penetration potential of vinclozolin in humans.

The in vivo rat study used dose application levels of 0.002, 0.02, 0.2 and 2 mg/cm^2 of skin (Hawkins et al, 1991). For each dose level subgroups of four rats were sacrificed at each of 0.5, 1, 2 4, 10 and 72 hours after dose application. The duration of exposure was 10 hours or up to the time of sacrifice, after which excess dose material was washed from the skin. The greatest percentage of applied material that was absorbed was seen with the lowest dose. At 10 hours (end of application) the systemic absorption was 13.3% with 11.9% of the dose left in the treated skin. The Agency calculated total exposure to be equal to the systemic plus skin amounts totaling 25.2%. This certainly exaggerates the daily exposure as the material in the skin would most likely not be completely absorbed within 24 hours.

Dermal absorption of vinclozolin was determined *in vitro* using rat and human epidermis in flow-through diffusion cells (Cameron and Jack, 1991). Vinclozolin was applied at dose levels of 0.2 and 0.002 mg/cm^2. The results are given in the following table.

	0.2 mg/cm^2			0.002 mg/cm^2		
	Human	Rat	Ratio	Human	Rat	Ratio
8 hr exposure (% of dose)	1.18	19.69	17	16.42	69.43	4
24 hr exposure (% of dose)	2.25	35.43	16	27.98	74.02	3
Max absorption rate (ug/cm^2/hr at high dose, Ng/cm^2/hr at low dose)	0.98	10.88	11	162.4	689.2	4

BASF Aktiengesellschaft
Product Safety
Regulations, Toxicology and Ecology

STATEMENT:
DERMAL PENETRATION OF VINCLOZOLIN

These results clearly demonstrate that the human skin is substantially less permeable to vinclozolin than rat skin. At the low dose of 0.002 mg/cm^2 which gave the highest dermal penetration amount in the *in vivo* rat study, the ratio of rat to human was approximately 4X based on amount absorbed and rate of penetration.

It is possible to combine the results of the *in vivo* and *in vitro* dermal penetration studies and estimate the dermal penetration of vinclozolin in humans. The maximum amount absorbed *in vivo,* as calculated by EPA, was 25.2% at 0.002 mg/cm^2. Adjusting by a 4X factor to account for less penetration in human skin, the dermal penetration is approximately 6%. Taking into account that the value of 25.2% is a worst case value, the true dermal penetration for humans is likely to be less than 6%. At higher exposure levels this would be substantially less based on lower penetration *in vivo* and higher ratios of rat to human penetration.

Conclusion

Results from both an *in vivo* dermal penetration study in rats and an *in vitro* dermal penetration study comparing rat to human skin can be combined to determine the human dermal penetration potential of vinclozolin. **The maximum human dermal penetration for vinclozolin would be 6%.**

Charles E. Hastings

Charles E. Hastings, Ph.D., DABT
Toxicology/Risk Assessment
BASF Corporation

STATEMENT:
DERMAL PENETRATION OF VINCLOZOLIN

References

(1) Hawkins, D.R. et al, (1991) The dermal absorption of ^{14}C-vinclozolin in the rat. Lab study no. HRC/BSF 478/901583. BASF RegDoc no. 91/10059. MRID no. 41587201.

(2) Cameron, B.D. and Jack, L. (1991) In vitro percutaneous absorption of [^{14}C]-Reg no 83258: a comparison using rat and human epidermis. Lab study no. 7656. BASF RegDoc no. 92/10221. MRID no.42483103.

BASF RESPONSE TO VINCLOZOLIN PRELIMINARY RISK ASSESSMENT CHRONIC EFFECTS TO WILDLIFE

The Agency has generated a Tier 1 risk assessment of chronic effects to wildlife. The method employed generates an expected environmental concentration (EEC) using the Kenaga nomogram. The EEC is than divided by the appropriate NOEL to calculate a Risk Quotient (RQ). An RQ >1 is considered by the Agency to be of concern. Some RQ values calculated for vinclozolin exceed this level of concern. BASF believes there is additional information which will allow the Agency to refine its dietary exposure assessments for avian and mammalian wildlife as they apply to vinclozolin use. Specifically, BASF believes the EEC calculations overestimate exposure by at least five times.

To calculate the EEC the Agency first estimated exposure using the Kenaga nomogram. The nomogram relates application rates to wildlife food residues. In this calculation the Agency has assumed that all acres of each crop are treated at the maximum labeled rate. In fact, the Agency has reliable data to show that this is not the case. Market share information is included in the Agency's Preliminary Risk Assessment. This information was developed by the Agency and transmitted in a document entitled "***Quantitative Useage Analysis for Vinclozolin***" dated November 3, 1999. That analysis shows that vinclozolin, in general, treats a small percentage of the total area of any individual crop and when used, vinclozolin is used at frequencies and rates much lower than the maximum the label would allow.

The assessment done was conducted on the use, which the Agency determined was the most conservative (i.e. the highest use rate and the highest number of applications). In this case, the use chosen was the onion use. Here the label allows a maximum of five applications at 1 pound active ingredient per acre. The data contained in the Useage Analysis shows that the average use pattern (when vinclozolin is used at all) is two applications at 0.5 pounds active ingredient per acre. While it may be appropriate to consider the most conservative exposure scenario when assessing chronic risk when there is no data concerning realistic average exposure, it is inappropriate to do so when there is reliable data available. In its assessment the Agency used both worst case and average residues from the appropriate Kenaga nomogram. As is appropriate for estimating chronic risk, BASF has estimated EEC values using the average use pattern information coupled with the average residue values from the Kenaga model. In all cases when compared to the appropriate NOEL, the RQ values are less than 1. The tables following this page list the RQ values determined by BASF. Even this assessment is a vast overestimation of exposure as the average percentage of the total onion acreage treated with vinclozolin is approximately 1%.

AVIAN CHRONIC RISK ASSESSMENT
BASED ON AVERAGE KENAGA VALUES AND AVERAGE APPLICATION RATES

CROP	SHORT GRASS		TALL GRASS		BROADLEAF PLANTS/ INSECTS		SEED/SM. INSECTS	
	EEC (PPM)	RQ	EEC (PPM)	RQ	EEC (PPM)	RQ	EEC (PPM)	RQ
SNAP BEANS	35	0.7	15	0.3	19	0.4	2.9	<0.1
LETTUCE	33	0.7	14	0.3	18	0.4	2.7	<0.1
RASPBERRIES	48	0.96	20	0.4	25	0.5	3.9	<0.1
ONIONS	23	0.5	14	0.2	18	0.2	2.7	<0.1
CANOLA	38	0.8	16	0.3	20	0.4	3	<0.1
TURF	33	0.7	14	0.3	17.5	0.4	2.8	<0.1

Average Use Rates: Based on EPA's Quantitative Useage Analysis:

Snap beans: 1.1 applications at 0.5 lb ai/A (0.6 lb ai/season)
Lettuce: 1.1 applications at 0.8 lb ai/A (0.9 lb ai/season)
Raspberries: 2.0 applications at 0.6 lb ai/A (1.2 lb ai/season)
Onions: 2.0 applications at 0.5 lb ai/A (1.0 lb ai/season)
Canola: 1.0 applications at 0.45lb ai/A (0.45 lb ai/season)
Turf: 1.0 applications at 1.0 lb ai/A (1.0 lb ai/season). For turf we have assumed that the entire 100,000 lb ai is used in the golf course market.

MAMMALIAN CHRONIC RISK ASSESSMENT
BASED ON AVERAGE KENAGA VALUES AND AVERAGE APPLICATION RATES

CROP	SHORT GRASS		TALL GRASS		BROADLEAF PLANTS/ INSECTS		SEED/SM. INSECTS	
	EEC (PPM)	RQ	EEC (PPM)	RQ	EEC (PPM)	RQ	EEC (PPM)	RQ
SNAP BEANS	35	0.1	15	<0.1	19	<0.1	2.9	<0.1
LETTUCE	33	0.1	14	<0.1	18	<0.1	2.7	<0.1
RASPBERRIES	48	0.2	20	<0.1	25	<0.1	3.9	<0.1
ONIONS	23	<0.1	14	<0.1	18	<0.1	2.7	<0.1
CANOLA	38	0.1	16	<0.1	20	<0.1	3	<0.1
TURF	33	0.1	14	<0.1	17.5	<0.1	2.8	<0.1

Average Use Rates: Based on EPA's Quantitative Useage Analysis:

Snap beans: 1.1 applications at 0.5 lb ai/A (0.6 lb ai/season)
Lettuce: 1.1 applications at 0.8 lb ai/A (0.9 lb ai/season)
Raspberries: 2.0 applications at 0.6 lb ai/A (1.2 lb ai/season)
Onions: 2.0 applications at 0.5 lb ai/A (1.0 lb ai/season)
Canola: 1.0 applications at 0.45lb ai/A (0.45 lb ai/season)
Turf: 1.0 applications at 1.0 lb ai/A (1.0 lb ai/season). For turf we have assumed that the entire 100,000 lb ai is used in the golf course market.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

June 6, 1996

MEMORANDUM

SUBJECT: Transmittal of EFED Reregistration Eligibility Summary for Vinclozolin

FROM: for Karen Angulo Kathy A. Monk
Science Analysis and Coordination Staff
Environmental Fate and Effects Division

THRU: Kathy Monk, Acting Chief Kathy A. Monk
Science Integration Staff,
Environmental Fate and Effects Division

TO: Mark Wilhite
Accelerated Reregistration Branch
Special Review & Reregistration Division

Attached are the following documents for the completed EFED summary report of Vinclozolin.

- EFGWB Science Chapter
- EEB Science Chapter
- SACS Reregistration Summary Report

1. General Information.

There are a number of outstanding environmental fate and effects data requirements. However, EFED believes there is sufficient information to complete a preliminary risk assessment for vinclozolin.

2. LOC Exceedences:

The major concern with vinclozolin is the chronic risk

to mammals and birds. Laboratory toxicity studies have demonstrated that vinclozolin has the potential to cause serious reproductive and developmental effects. Vinclozolin has been shown to cause antiandrogenic effects in laboratory rats. It should be noted that mammalian hormone disruption may indicate potential problems in avian species. The implication of environmental hormone disruption coupled with avian chronic LOC exceedences, based on conventional reproductive test results, suggests high chronic risk to birds.

Birds: Vinclozolin poses a chronic risk to birds. Risk quotients exceed the chronic risk LOC (1.0) for all use sites for both single and multiple applications.

Mammals: Vinclozolin poses a chronic risk to mammals. Risk quotients exceed the chronic risk LOC (1.0) for several use sites for single applications and all use sites for multiple applications.

3. <u>Data Requirements and Value of the Information</u>.

Listed below are the unfulfilled environmental fate data requirements, the information needed to fulfill them, and the value of each study.

a. **Environmental Fate.** Data indicate that parent vinclozolin is relatively labile and dissipates in the environment by microbial-mediated hydrolysis (soil metabolism), abiotic degradation, and transport with water. There are several principal degradation products of vinclozolin that EFED considers to be very important. Metabolite B is formed rapidly and in relatively large concentrations, and may have biological activity and contribute to the pesticidal properties of parent vinclozolin. Metabolites B, D, and E are potentially very mobile to slightly mobile and may be transported with water through the soil profile or with surface runoff. Residues are likely to be most mobile in sandy soils low in organic matter.

As you will note below, EFED is requesting additional information about vinclozolin's degradates. This information will allow EFED to further characterize the exposure potential from this chemical.

1) **Hydrolysis (161-1).** Because hydrolysis is an important degradation process for vinclozolin, additional evidence (e.g. a proposed mechanism for re-formation of parent and the kinetics for the

reaction) is needed to support the hydrolysis results for pH 5.

2) **Photodegradation on soil (161-3).** The registrant should: (a) explain the presence of large quantities of metabolite S at time zero and later in the study, including dark controls; and (b) provide data that demonstrate that the artificial light source used compares favorably with natural sunlight.

3) **Aerobic soil metabolism (162-1), and**
4) **Terrestrial field dissipation (164-1).** Frozen storage stability data for individual analytes (vinclozolin and metabolites B, D, and E) in soil are needed to increase confidence in the aerobic soil metabolism and field dissipation studies. This information is important because much of EFED's assessment is based on four field dissipation studies.

5) **Leaching and adsorption/desorption (163-1).** The registrant should explain the inconsistencies between K_d and corresponding K_{dcs} values in the batch equilibrium studies for parent vinclozolin and metabolites D and E.

Metabolite B is an important degradate and K_d values for four soils should be submitted. K_ds for metabolite B will enable a more precise assessment of the potential mobility of this key degradation product, which is formed early in the degradation process in relatively large concentrations. In addition, this information may also be needed for modeling simulations that assess the potential of vinclozolin residues to contaminate surface waters. Given its rapid formation, it is possible that metabolite B has biological activity and contributes to the pesticidal properties of vinclozolin. Soil column studies indicate that metabolite B is potentially mobile, but the information available from these studies is only qualitative.

6) **Spray drift.**

No vinclozolin-specific studies were reviewed. Droplet size spectrum (201-1) and drift field evaluation (202-1) studies were required since the different products may be applied by aircraft and due to the concern for potential risk to nontarget

aquatic organisms. However, to satisfy these requirements the registrant in conjunction with other registrants of other pesticide active ingredients formed the Spray Drift Task Force (SDTF). The SDTF has completed and submitted to the Agency its series of studies which are intended to characterize spray droplet drift potential due to various factors, including application methods, application equipment, meteorological conditions, crop geometry, and droplet characteristics. During 1996 EPA plans to evaluate these studies. In the interim and for this assessment of vinclozolin the Agency is relying on previously submitted spray drift data and the open literature for off-target drift rates. After its review of the new studies the Agency will determine whether a reassessment is warranted of the potential risks from the application of vinclozolin.

Generally, submission of the requested information will enhance EFED's confidence in the data, but is not likely to affect substantially the environmental fate assessment for vinclozolin. However, two studies are particularly important (leaching and adsorption/desorption [163-1], and aerobic soil metabolism [162-1]). This information is important because much of EFED's assessment is based on four field dissipation studies.

In addition, the following data may be necessary. (SRRD has said that they think the forestry use is not a use which should be considered. However, because it is in the LUIS report we have included it here. If we should not consider this use, please provide us with written guidance to disregard the LUIS.)

7) **Forestry uses.** The LUIS report indicates that there are forestry uses for vinclozolin. Application to forests is likely to result in exposure to bodies of water and in dissipation patterns that may not be addressed by the terrestrial use data set. Because the forestry use could result in exposure to aquatic systems from foliar application to broadleaf trees and conifers, aerobic aquatic metabolism data (162-3) should be submitted. Also, forest field dissipation data (164-3) are needed to assess the fate of vinclozolin under typical forest use conditions. Neither of these studies has been submitted.

b. Ecological Effects.

1) **Aquatic invertebrate life-cycle (freshwater and marine) [72-4 (b)].** The need for these studies is high because vinclozolin and its degradates may be relatively persistent and repeated applications result in repeated exposure. These studies are needed to complete a chronic risk assessment for all vinclozolin use sites.

2) **Freshwater fish life-cycle and life-stage.** The need for these studies is high because vinclozolin is relatively persistent and repeated applications results in repeated exposure. These studies are needed to complete a chronic risk assessment for all vinclozolin use sites. The following are required:

- freshwater fish life-cycle study with technical vinclozolin (72-5).
- freshwater fish life-stage study with technical vinclozolin. (72-4)
- freshwater fish life-stage study with metabolite B. (72-4)
- freshwater fish life-stage study with metabolite E. (72-4)

3) **Acute Toxicity to estuarine/marine fish, mollusk, and shrimp [72-3 (a,b;c)].** The need for this study is relatively low because it appears that vinclozolin poses a low acute risk to freshwater fish and invertebrates.

4) **Aquatic plant growth (122-2).** The need for this study to be repeated at a test concentration of 2.6 ppm (the solubility level of vinclozolin) is relatively low because vinclozolin does not appear to adversely effect aquatic plants substantially at nominal test concentrations of 1.0 ppm.

4. <u>Relative Chronic Risk for Vinclozolin Use Sites</u>.

The extent of chronic risk to wild mammals and birds differs among use sites. The amount of acreage to which vinclozolin is applied, application rates, number of applications, application methods, and the amount of wildlife utilization during breeding periods all impact

risk. The timing of application, geographic location, and attractiveness of the use site affect the amount of use by wildlife during breeding periods. Considering the aforementioned factors, a course ranking of relative risk for vinclozolin use sites follows.

High Risk Sites

Strawberries: A relatively large proportion of the vinclozolin presently used in the U.S. is applied to strawberries. Vinclozolin may be applied multiple times during wildlife breeding periods.

Stone fruits: Vinclozolin may be applied multiple times during wildlife breeding periods, and there may be high wildlife use following application.

Medium Risk Sites

Lettuce: A relatively large proportion of the vinclozolin presently used in the U.S. Multiple applications during wildlife breeding periods.

Onions: Multiple applications during the growing season.

Chicory, raspberries, turf: Vinclozolin may be applied during wildlife breeding periods, and there may be wildlife use following application.

Lower Risk Sites

Ornamentals: Multiple applications during wildlife breeding periods. Can be applied to bare soil.

Kiwi fruit: Multiple applications during the growing season.

5. **Risk Reduction Measures.**

Reducing chronic risk to nontarget terrestrial and aquatic organisms would require reducing application rates, number of applications per year and/or changing the timing of applications. Several vinclozolin labels do not provide specific maximum application rates and number of applications per season limits. All vinclozolin labels should be required to specify maximum application rates and numbers of applications for each use site.

6. **Label Statements.**

a. **Ground Water.** Vinclozolin degradates have the potential to contaminate ground water. For this reason, EFED recommends that all product labels carry the following advisory:

> "This chemical demonstrates the properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination."

Because the reference dose and carcinogenicity of vinclozolin are under review, a final assessment of the human health effects from drinking water cannot be established at this time. After the peer review committee meeting, further recommendations related to ground water will be made.

b. **Surface Water.** EFED does not currently believe that the potential risks of vinclozolin to aquatic non-target organisms is sufficient to warrant a surface water advisory on the label. However, EFED defers to HED on whether a surface water advisory is necessary to protect surface drinking water supplies. If a decision is made to generate a labeling surface water advisory for vinclozolin, EFED will recommend a label statement.

c. **Manufacturing use.** EFED is not aware of any manufacturing use labels for vinclozolin. If there are registered MUPs, the precautionary labeling should read as follows:

> "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewer treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA"

d. **End-use.** The following label statement is necessary for all end-use labels.

> "Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean water mark. Do not contaminate water when disposing of equipment washwaters or rinsate."

If you have questions, please contact Karen Angulo at 305-5011.

cc: Denise Keehner
Hank Jacoby
Dan Balluff
Rachelle Kudrik
Tony Maciorowski
Doug Urban
Skee Jones
Kathy Monk
Harry Craven
Jay Ellenberger

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Toxicity Data

a. Toxicity to Terrestrial Species

(1) Birds, Acute and Subacute Toxicity

In order to establish the toxicity of vinclozolin to birds, the following tests are required: one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail); two subacute dietary studies (LC_{50}) on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail). The following tables provide avian acute and dietary toxicity data:

Avian Acute Oral Toxicity					
Species	**% A.I.**	**LD_{50} (mg/kg)**	**MRID No. Author/Year**	**Toxicity Category**	**Fulfills Guideline Requirement**
Northern bobwhite	96.5	> 2,510[1]	92194-002 Fink, 1978	practically nontoxic	Yes

1 No mortality occurred at any level tested.

Avian Subacute Dietary Toxicity					
Species	**% A.I.**	**LC_{50} (ppm)**	**MRID No. Author/Year**	**Toxicity Category**	**Fulfills Guideline Requirement**
Northern bobwhite	96.5	>5,620[1]	92194-003 Fink, 1978	practically nontoxic	Yes
Mallard duck	96.5	>5,620[2]	92194-003 Fink, 1978	practically nontoxic	Yes

1 No dose related response occurred at any level tested.
2 No mortality occurred at any level tested.

These results indicate that vinclozolin is practically nontoxic to avian species on an acute oral and subacute dietary basis. The guideline requirements for acute oral (LD50) and subacute dietary (LC50) are fulfilled. (MRIDs 92194-003 and 92194-002)

(2) Birds, Chronic Toxicity

Avian reproduction studies are required when birds may be exposed repeatedly or continuously through persistence, or multiple applications. Environmental fate data indicate that vinclozolin may be relatively persistent and product labeling allows multiple applications per growing season. The following table provides avian chronic toxicity data:

Avian Reproduction					
Species	**% A.I.**	**NOEC (ppm)**	**LOEL**	**MRID/Accession No. Author/Year**	**Fulfills Guideline Requirement**
Northern bobwhite quail	97%	50	Fertility appeared to be reduced in treatment groups (5 and 50 ppm) compared to controls but not significantly ($p > .05$).	070698 Roberts/1982	Partially
Mallard duck	97%	Not Determined	At 50 ppm fertility rate was reduced. Data also suggest that the number of viable eggs of eggs set were reduced and testicular development may have been affected at the lowest test concentration (5 ppm).	070698 Roberts/1982	Partially
Mallard duck	9.4%	>50 (highest dose level tested)	This study was designed to evaluate effects on male fertility. No statistically significant reduction was seen at any test concentration.	7969-62, 7969-63 Munk, R. 1987	Partially[1]
Northern bobwhite quail	99.73%	50	125 ppm, based on significantly reduced eggs laid, egg shell thickness, and proportion of 14 day old survivors of hatched chicks.	428689-01 Munk, R. 1993	Partially[2]
Mallard duck	99.7%	125	250 ppm, based on significantly reduced hatching success ($P < 0.05$). The proportion of dead chicks in the shell of viable embryos were reduced (although not significantly) compared to controls at all treatment levels (25, 125 and 250 ppm).	428275-01 Johnson, A.J. 1993	Partially[2]

1 This was a special test. The study protocol did not follow the design for the standard 71-4 guideline requirement.

2 The actual concentration resulting in the known effects is questionable because in the case of the avian reproductive studies conducted 1993, the test material was a dry powder and a vehicle such as corn oil was not used. Results of the analytical measurements of homogeneity of the mixing process do not necessarily reflect the extent to which the test material may have settled to the bottom of the feed trays during the exposure periods, thereby limiting exposure to birds.

The results indicate that vinclozolin demonstrates an NOEC of 50 ppm based on an LOEC of 125 ppm for bobwhite quail. The above avian studies collectively fulfill avian reproduction guideline requirements. (MRIDs 070698, 7969-62, 7969-63, 428275-01, 428689-01)

(3) Mammals, Acute Toxicity

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics. In most cases, however, an acute oral LD_{50} study from the Agency's Health Effects Division (HED) is used to determine toxicity to mammals. The lowest LD_{50} value for laboratory rats is reported in the table below.

Mammalian Acute Oral Toxicity			
Species	LD_{50} mg/kg	MRID #	Toxicity Category
Rat	> 10,000[1]	00086336 92194010	III

1 No mortality occurred at any dose level.

The available mammalian data indicate that vinclozolin is practically nontoxic to small mammals on an acute oral basis (MRID #421676-02)

(4) Mammals, Chronic Toxicity

Mammal reproduction studies required by the Agency's Health Effects Division (HED) are used to determine chronic toxicity to mammals. The NOEL and LOEL for laboratory rats are reported in the table below.

Mammalian Chronic Toxicity					
Species	% A.I.	Study type	NOEL	LOEL	Accession/ MRID No.
Rat	99.2	Reproduction - 2 generation	50 ppm (4.9 mg/kg/day)	300 ppm (30 mg/kg/day) based on epididymal weight reduction. Adult male offspring sired no offspring at 1,000 and 3,000 ppm. Genital and reproductive tract malformations (including hypospadia) occurred at 1,000 and 3,000 ppm. Fertility in adult female offspring may have been reduced at 3,000 ppm.	425813-01 425813-02

Rat	99.6	Developmental toxicity	15 mg/kg/day	50 mg/kg based on decreased anal-genital distance in males.	411322-01

Additional data (MRID 43170501)[1] indicate that vinclozolin treatment induces antiandrogenic endocrine disruption including: a dose dependent reduction of anal-genital distance (AGD), retained nipples, and reduction in ventral prostrate and seminal vesicle gland weights in male rat offspring at 12, 25, 50 and 100 mg/kg/day. Doses of 50 mg/kg/day produced subtle, reversible reductions in AGD shortly after birth. These effects were considered to be minimal (by HED). This research has been reviewed by the Health Effects Research Laboratory, U.S. EPA and approved for publication.

(5) Insects, Acute Toxicity

A honey bee acute contact LD_{50} study is required if the proposed use will result in honey bee exposure. Acute toxicity data for honey bees are provided in the table below.

Honey Bee Acute Contact Toxicity					
Species	**% A.I.**	**LD_{50} (ug/bee)**	**MRID/Acc No. Author/Year**	**Toxicity Category**	**Fulfills Guideline Requirement**
Honey bee	99.2	> 100	409928-01 Hoxter, K.A. 1988	practically nontoxic	Yes

The data indicate that vinclozolin may be characterized as practically nontoxic to honey bees with an LD50 value of > 100 ug/bee (Acc. No. 409928-01). The guideline requirement is fulfilled.

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[1] Gray, L. E. Jr., Ostby, J., Monosson, E., and Kelce, W.R. (1995). Environmental antiandrogens: effects of low doses of the fungicide vinclozolin on sexual differentiation of the male rat. In press.

b. Toxicity to Aquatic Organisms

(1) Freshwater Fish, Acute Toxicity

In order to establish the toxicity to freshwater fish, the minimum data required are two freshwater fish toxicity studies. One study should use a coldwater species (preferably the rainbow trout), and the other should use a warmwater species (preferably the bluegill sunfish). Acute toxicity data for freshwater fish are provided in the table below.

Freshwater Fish Acute Toxicity Findings

Species	% A.I.	LC_{50} (ppm)	MRID/Acc. No.	Toxicity Category	Fulfills Guideline Requirement
rainbow trout	50% (Ronilan 50W)	>13.6 (a.i)	264302 Gelbke, H.P., 1980	slightly toxic	partially
rainbow trout	50% (Ronilan FL)	> 50 (a.i.)	413251-01 BASF, 1989	slightly toxic	partially
rainbow trout	97%	2.84	264302 Gelbke, H.P., 1980	moderately toxic	yes
pumpkinseed Lepomis gibbosus	97%	>3.4	264302 Gelbke, H.P. 1980	moderately toxic	yes

These results indicate that technical vinclozolin is moderately toxic to freshwater fish on an acute basis. The guideline requirement is fulfilled. (MRID 264302)

(2) Freshwater Fish, Chronic Toxicity

The fish life-cycle test is required when an end-use product is expected to be transported to water from the intended use site and when studies of other organisms indicate that the reproductive physiology of fish and/or invertebrates may be effected. Vinclozolin can be applied repeatedly during the growing season to most crops and, in addition, reproductive impairment has been seen in birds and mammals. Parent vinclozolin and two of its metabolites B and E (as described elsewhere in this chapter) have been shown to compete with androgen receptors in mammalian tissue culture studies. The following studies are required:

1) Freshwater fish life-cycle study with technical vinclozolin.

2) Freshwater fish early life-stage with technical vinclozolin.

3) Freshwater fish early life-stage with metabolite B.

4) Freshwater fish early life-stage with metabolite E.

No chronic freshwater fish studies have been submitted, therefore, the guideline requirement is not fulfilled.

(3) Freshwater Invertebrates, Acute Toxicity

The minimum testing required to assess the hazard of a pesticide to freshwater invertebrates is a freshwater aquatic invertebrate toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges. Acute toxicity data for freshwater invertebrates are provided in the table below.

Freshwater Invertebrate Toxicity Findings

Species	% A.I.	EC_{50} (ppm)	MRID NO. Author/Year	Toxicity Category	Fulfills Guideline Requirement
Daphnia magna	96.5%	4.0 ppm	Union Carbide Environmental Services 4/28/1978	practically nontoxic	Yes

There are sufficient data to characterize vinclozolin as practically nontoxic to aquatic invertebrates. The guideline requirement is fulfilled (Union Carbide 1978).

(4) Freshwater Invertebrates, Chronic Toxicity

An aquatic invertebrate life-cycle study is required if the pesticide is expected to be transported to water from the intended use site or if the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity. Vinclozolin can be applied repeatedly during the growing season to most crops and, in addition, reproductive

impairment has been seen in birds and mammals. Parent vinclozolin and two of its metabolites have been shown to compete with androgen receptors in mammalian tissue culture studies. An aquatic invertebrate life-cycle study with technical vinclozolin is required. No chronic freshwater invertebrate studies have been submitted, therefore, the guideline requirement is not fulfilled.

(5) Estuarine and Marine Fish and Invertebrates, Acute Toxicity

Acute toxicity testing with estuarine and marine organisms **using the TGAI** is required when an end-use product is expected to reach the marine estuarine environment in significant concentrations. The use of vinclozolin on several sites (such as stone fruits, strawberries, and lettuce) may result in exposure to the marine/estuarine environment.

The requirements under this category include a 96-hour LC_{50} for an estuarine fish, a 96-hour LC_{50} for shrimp, and either a 48-hr embryo-larvae study or a 96-hour shell deposition study with oysters. No data are available to characterize the acute toxicity of vinclozolin to estuarine/marine organisms. The guideline requirements are not fulfilled.

(6) Estuarine and Marine Organisms, Chronic Toxicity

The estuarine fish and invertebrate tests are required when an end-use product is expected to be transported to water from the intended use site and when studies of other organisms indicate that the reproductive physiology of fish and/or invertebrates may be effected. Vinclozolin can be applied repeatedly during the growing season to such sites as stone fruits, strawberries, and lettuce. This may result in exposure to the marine/estuarine environment. In addition, reproductive impairment has been seen in birds and mammals. Parent vinclozolin and two of its metabolites have been shown to compete with androgen receptors in mammalian tissue culture studies. The estuarine/marine chronic study is reserved pending the results of the acute estuarine studies and the freshwater chronic studies.

c. Toxicity to Aquatic Plants

Currently, aquatic plant testing is required for any fungicides that have outdoor non-residential terrestrial uses that may result in movement off-site due to by drift. The following species should be tested at the tier I level: *Selenastrum capricornutum*, and *Lemna gibba*, because several of the uses, such as the use on various stone fruit, may result in exposure through drift. Results from Tier I toxicity testing with vinclozolin are provided in the table below.

Nontarget Aquatic Plant Toxicity Findings

Species	% A.I.	Effect Level (ppm a.i.)	MRID No. Author/year	Fulfills data requirements
Selenastrum capricornutum	98%	growth reduced by 1.2% at 1.02	423947-01 Alexander, M.M. 1992	partially
Anabaena Flos-aquae	98%	stimulated growth by 3.9% at 1.01	423947-02 Alexander, M.M. 1992	partially
Skeletonema costatum	98%	inhibited growth by 3.8% at 0.87	423947-04 Alexander, M.M. 1992	partially
Lemna gibba	98%	stimulated growth by 7.9% at 0.90	423947-05 Alexander, M.M. 1992	partially
Navicula pelliculosa	98%	stimulated growth by 94.5% at 1.06	423947-03 Alexander, M.M. 1992	partially

A $\geq$ 50% adverse effect to plants was not observed in the above Tier I toxicity testing. However, plants were tested only up to 1 ppm (nominal concentration). Vinclozolin may be applied at up to 8.7 lbs ai/acre and direct application to six inches of water at this rate would result in a residue level of 6.4 ppm. The concentration in the Tier I tests was not high enough to evaluate effects at this level. Therefore, the guideline requirement is not fulfilled and the Tier I tests should be repeated with Selenastrum capricornutum and Lemna gibba at a test concentration of 2.6 ppm (the solubility level of vinclozolin).

2. Environmental Fate.

Although several environmental fate data requirements are unfulfilled at this time (hydrolysis [161-1], photodegradation on soil [161-3], aerobic soil metabolism

[162-1], leaching and adsorption/desorption [163-1], and terrestrial field dissipation [164-1]), there is sufficient information to allow a qualitative environmental fate assessment for vinclozolin.

a. Environmental Fate Assessment.

Acceptable and supplemental laboratory and field data indicate that parent vinclozolin is relatively labile and dissipates in the environment by microbial-mediated hydrolysis, soil metabolism, abiotic degradation, and transport with water. N-(3,5-dichlorophenyl) carbamic acid (1-carboxyl-1-methyl)-2-propenyl ester (metabolite B or BF 352-22) is a common degradate of hydrolysis, soil metabolism, and photolysis. Because metabolite B is formed rapidly and in relatively large concentrations at environmental pH, it may have biological activity and contribute to the pesticidal properties of parent vinclozolin. The other principal degradation products of vinclozolin are 3,5-dichloroaniline (metabolite D or BF 352-31); and N-(3,5-dichlorophenyl)-2-hydroxy-2-methyl-3-butenoic acid amide (metabolite E or BF 352-23). Other degradates are formed in smaller concentrations. Metabolite E (which appears to be a degradation product of parent and metabolite B) degrades to 3,5-dichloroaniline (metabolite D), which appears to resist further degradation. Metabolites B, D, and E are potentially very mobile to slightly mobile and may be transported with water through the soil profile or with surface runoff. Residues are likely to be most mobile in sandy soils low in organic matter. Vinclozolin residues did not accumulate significantly in bluegill sunfish.

b. Environmental Fate and Transport

(1) Degradation

(a) **Hydrolysis.** In an upgradeable study that partially fulfills the data requirement, vinclozolin hydrolyzed at pH 7 and 9 with respective half-lives of 31.3 hr and 37.9 min. Two major degradates were identified: 1) N-(3,5-dichlorophenyl)carbamic acid (1-carboxy-1-methyl)-2-propenyl ester (BF 352-22 or metabolite B), and 2) N-(3,5-dichlorophenyl)-2-hydroxy-2-methyl-3-butenoic acid amide (BF 352-23 or metabolite E). At pH 5, where vinclozolin and metabolite B appeared to reach chemical steady-state in 5 days, a half-life of 41.8 days was calculated for parent. The half-life for combined residues of parent and metabolite B was 89.4 days.

The guideline requirement (161-1) is not fulfilled. Hydrolysis is an important degradation process for vinclozolin, therefore, additional evidence (e.g. a proposed mechanism for re-formation of parent and the kinetics for the reaction) is needed to support the

hydrolysis results for pH 5. (MRID 41471006)

(b) **Photodegradation in water.** In an acceptable study that fulfills the data requirement, vinclozolin in pH 5 buffered solution exposed to simulated sunlight in 12 hour light/12 hour dark periods degraded with a half-life of 15.9 days; in dark controls the half-life was 38.1 days. In addition to parent, metabolites B and E were the major compounds identified. The guideline requirement (161-2) is fulfilled. (MRID 42394706)

(c) **Photodegradation on soil.** In an upgradeable study, vinclozolin applied to a sandy loam soil irradiated with simulated sunlight on a 12 hr light/12 hr dark cycle degraded with a half-life of 18.1 days. The following three degradates were detected in irradiated samples: metabolites B, E, and N-(3,5-dichlorophenyl)-5-methyl-2,4-oxazolidinedione (metabolite S or BF 352-41). In dark controls, where the half-life was 37.2 days, metabolites B and S were important degradates. (MRID 41471008)

The guideline requirement (161-3) is not fulfilled. The following information is needed: 1) information explaining the presence of large quantities of metabolite S at time zero and later in the study, including dark controls, and 2) data that demonstrates that the artificial light source used compares favorably with natural sunlight.

(d) **Aerobic soil metabolism.** In upgradeable aerobic soil metabolism studies, vinclozolin degraded with half-lives of 35-53 days. In separate experiments conducted in a German soil, degradation appeared to be biphasic with early initial rapid degradation ($t_{1/2}$ = 5-7 days) followed by slower degradation ($t_{1/2}$ = 46-50 days). In a supplemental study where an exaggerated application rate appeared to affect degradation kinetics, vinclozolin's half-life was 352 days. Mineralization to CO_2 was minimal. Metabolites B, E, and D (3,5-dichloroaniline) were the principal degradates.

The guideline requirement (162-1) is not fulfilled. Frozen storage stability data for individual analytes (vinclozolin and metabolites B, D, and E) are needed. (MRIDs 88288, 136376, 136377, 43013001)

(e) **Anaerobic soil metabolism.** In an acceptable study that fulfills the data requirement, vinclozolin was applied to a loamy sand soil and incubated aerobically for 14 days followed by a 62-day

anaerobic incubation period. The anaerobic half-life was 17.6 days. For aerobic and anaerobic conditions, the half-life was 15.33 days. Metabolites B, E, and D were the principal degradates. The guideline requirement (162-2) is fulfilled. (MRID 41471009)

(f) **Anaerobic aquatic metabolism (162-4).** In a supplemental study where an exaggerated application rate appeared to affect degradation kinetics vinclozolin added to a flooded loamy sand soil degraded with a half-life of 134 days. The half-life of vinclozolin in sediment alone was 87.4 days. The principal degradation products were metabolites B, D, and E. The guideline requirement (162-2) is fulfilled. (MRID 43013002)

(2) **Mobility.**

(a) **Leaching and adsorption/desorption.** Upgradeable batch equilibrium studies for parent vinclozolin (MRID 41471010) and metabolites D and E indicate that vinclozolin and its principal degradates are potentially very mobile to slightly mobile in soil. Freundlich K_d values of 0.46, 3.82, 3.4, and 5.27 were reported for vinclozolin in sand, sandy loam, loam, and clay loam soils, respectively. K_ds for metabolite D were 0.58, 1.86, 2.60, and 10.01 for sand, sandy loam, loam, and clay loam soils, respectively. Metabolite E K_ds in the same soils were 0.65, 1.24, 1.66, and 6.73. Adsorption increased with soil organic matter, clay content, and cation exchange capacity. Column leaching studies indicate that parent and degradates, including metabolite B, are potentially mobile.

The guideline requirement (163-1) is not fulfilled. Information is needed explaining the inconsistencies between K_d and corresponding K_{des} values in the batch equilibrium studies for parent vinclozolin and metabolites D and E. Also, because metabolite B is an important degradate, K_d values for metabolite B should be submitted for four soils. K_ds for metabolite B will enable a more precise assessment of the degradate's potential mobility and may also be needed for modeling. (MRID 41888904, 136381, 4149-6904)

(b) **Laboratory volatility.** In an acceptable study that fulfills the data requirement, volatilization of vinclozolin from a sand soil did not exceed 7.1% of the applied radioactivity. Most volatile radioactivity was detected as vinclozolin; small amounts of ^{14}C were

detected in metabolites B and E and in unidentified compounds. Volatilization increased with soil moisture and air flow. The guideline requirement (163-2) is fulfilled. (MRID 42513101)

(3) **Bioaccumulation in fish.**

In an acceptable studies that fulfill the data requirement, bluegill sunfish exposed to vinclozolin residues exhibited bioconcentration factors of 143X, 421X, and 279X for edible, non-edible, and whole fish tissue, respectively. Vinclozolin and metabolites S and D were detected in fish tissue. The guideline requirement (165-4) is fulfilled. (MRIDs 136387 and 42847001)

(4) **Field Dissipation.**

(a) **Terrestrial field dissipation.** In upgradeable terrestrial field dissipation studies conducted in FL, NY, MO, and CA vinclozolin dissipated with linear half-lives of 34 to 94 days. Half-lives for total residues (vinclozolin plus its dichloroaniline-containing metabolites) were 179 to >1000 days. Nonlinear DT_{50}s (the time needed for 50% decline in initial concentration) for total residues were 30 to 300 days. DT_{90}s of >2500 days for total residues were reported in MO and NY. Persistence of total residues appeared to be attributable to the resistance of metabolite D (dichloroaniline) to degradation and to the inclusion of soil-bound residues in the data. Intermittent detections of residues were reported at soil depths of 12-18, 18-24, and 24-30 inches. Metabolite D was detected regularly deeper than 6 inches. Residues may accumulate and be available for rotational crop uptake.

The guideline requirement (164-1) is not fulfilled. (MRIDs 41538301, 42687601, 42717401, 43505907)

(5) **Spray Drift.**

No vinclozolin-specific studies were reviewed. Droplet size spectrum (201-1) and drift field evaluation (202-1) studies were required since the different products may be applied by aircraft and due to the concern for

potential risk to nontarget aquatic organisms. However, to satisfy these requirements the registrant in conjunction with other registrants of other pesticide active ingredients formed the Spray Drift Task Force (SDTF). The SDTF has completed and submitted to the Agency its series of studies which are intended to characterize spray droplet drift potential due to various factors, including application methods, application equipment, meteorological conditions, crop geometry, and droplet characteristics. During 1996 EPA plans to evaluate these studies. In the interim and for this assessment of vinclozolin the Agency is relying on previously submitted spray drift data and the open literature for off-target drift rates. The rates are 1% of the applied spray volume from ground applications and 5% from aerial and orchard airblast applications at 100 feet downwind. After its review of the new studies the Agency will determine whether a reassessment is warranted of the potential risks from the application of vinclozolin to nontarget organisms.

c. Water Resources.

(1) Ground Water. Because degradates of vinclozolin are mobile and can be persistent under certain environmental conditions, the chemical has the potential to contaminate ground water and impact ground-water quality.

(2) Surface Water. Vinclozolin can be transported to surface water via spray drift. Also, vinclozolin and its degradates could reach surface water with runoff.

3. Exposure and Risk Characterization

a. Ecological Exposure and Risk Characterization

Explanation of the Risk Quotient (RQ) and the Level of Concern (LOC): The Levels of Concern are criteria used to indicate potential risk to nontarget organisms. The criteria indicate that a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms. There are two general categories of LOC (acute and chronic) for each of the four nontarget faunal groups and one category (acute) for each of two nontarget floral groups. In order to determine if an LOC has been exceeded, a risk quotient must be derived and compared to the LOC's. A risk quotient is calculated by

dividing an appropriate exposure estimate, e.g. the estimated environmental concentration (EEC), by an appropriate toxicity test effect level, e.g. the LC_{50}. The acute effect levels typically are:

-EC_{25} (terrestrial plants),

-EC_{50} (aquatic plants and invertebrates),

-LC_{50} (fish and birds), and

-LD_{50} (birds and mammals)

The chronic test results are the NOEL (sometimes referred to as the NOEC) for avian and mammal reproduction studies, and either the NOEL for chronic aquatic studies, or the Maximum Allowable Toxicant Concentration (MATC), the geometric mean of the NOEL and the LOEL (sometimes referred to as the LOEC) for chronic aquatic studies. When the risk quotient exceeds the LOC for a particular category, risk to that particular category is presumed to exist. Risk presumptions are presented along with the corresponding LOC's.

Levels of Concern (LOC) and Associated Risk Presumption

Mammals, Birds

IF THE	LOC	PRESUMPTION
acute RQ>	0.5	High acute risk
acute RQ>	0.2	Risk that may be mitigated through restricted use
acute RQ>	0.1	Endangered species may be affected acutely
chronic RQ>	1	Chronic risk to endangered and non-endangered species occur

Fish, Aquatic invertebrates

IF THE	LOC	PRESUMPTION
acute RQ>	0.5	High acute risk
acute RQ>	0.1	Risk that may be mitigated through restricted use
acute RQ>	0.05	Endangered species may be affected acutely
chronic RQ>	1	Chronic risk to endangered and non-endangered species may occur

Plants

IF THE	LOC	PRESUMPTION
RQ>	1	High risk
RQ>	1	Endangered plants may be affected

Currently, no Level of Concern (LOC) has been established for acute restricted use or chronic effects for plants.

(1) Exposure and Risk to Terrestrial Animals

(a) Acute Risk to Birds

Maximum estimated residue levels for dietary food items following vinclozolin applications may be compared to avian dietary LC_{50} values to assess hazard. The maximum concentration of vinclozolin residues on selected dietary food items following both a single and multiple applications and the corresponding avian acute risk quotients (RQ) are provided in the table below.

Estimated Environmental Concentrations (EEC) and Avian Acute Risk Quotients (RQ) (based on EEC/the highest test concentration in the avian dietary LC50 studies, 5,620 ppm)

Use site; maximum single application rate; maximum seasonal application rate; and method of application	**Food items** (maximum residue level following a 1 lb ai/acre application Fletcher, 1994)	**EEC** (1 application)	**EEC** (multiple applications with no degradation)	**Acute RQ** (1 application)	**Acute RQ** (multiple applications)
Apricot, Cherry Nectarine, Peach 1 lb ai/acre; 4.2 lbs ai/acre/year; aerial or ground application	**Short grass** (240 ppm)	240 ppm	1,008 ppm	< 0.04	< 0.2
	Long grass (110 ppm)	110 ppm	462 ppm	< 0.02	< 0.1
	Broadleaf plants/ small insects (135 ppm)	135 ppm	567 ppm	< 0.01	< 0.1
	Fruits/large insects/seeds (15 ppm)	15 ppm	63 ppm	< 0.002	< 0.01
Chicory (California) 0.0002 lb ai/sq ft (8.7 lbs ai/acre); 8.7 lbs ai/acre/year; ground application	**Short grass** (240 ppm)	2,088 ppm	N/A	< 0.4	N/A
	Long grass (110 ppm)	957 ppm	N/A	< 0.2	N/A
	Broadleaf plants/ small insects (135 ppm)	1,175 ppm	N/A	< 0.2	N/A
	Fruits/large insects/seeds (15 ppm)	131 ppm	N/A	< 0.02	N/A
Kiwi fruit (California, South Carolina) 2.0 lbs ai/acre; 4.0 lbs ai/acre/year; ground application	**Short grass** (240 ppm)	480 ppm	960 ppm	< 0.1	< 0.2
	Long grass (110 ppm)	220 ppm	440 ppm	< 0.04	< 0.1
	Broadleaf plants/ small insects (135 ppm)	270 ppm	540 ppm	< 0.05	< 0.1
	Fruits/large insects/seeds (15 ppm)	30 ppm	60 ppm	< 0.005	< 0.01

Estimated Environmental Concentrations (EEC) and Avian Acute Risk Quotients (RQ)
(based on EEC/the highest test concentration in the avian dietary LC50 studies, 5,620 ppm)

Use site; maximum single application rate; maximum seasonal application rate; and method of application	**Food items** (residue level following a 1 lb ai/acre application Fletcher, 1994)	EEC (1 application)	EEC (multiple applications with no degradation)	**Acute RQ** (single application)	**Acute RQ** (multiple applications)
Onion (dry bulb type) 1.0 lb ai/acre; 5.2 lbs ai/acre/year; ground application 3" band over the row (24" row space)	**Short grass** (240 ppm)	1,920 ppm (within the band)	9,984 ppm (within the band)	< 0.3	< 1.8
	Long grass (110 ppm)	880 ppm (within the band)	4,576 ppm (within the band)	< 0.2	< 0.8
	Broadleaf plants/ small insects (135 ppm)	1,080 ppm (within the band)	5,616 ppm (within the band)	< 0.2	< 1.0
	Fruits/large insects/seeds (15 ppm)	120 ppm (within the band)	624 ppm (within the band)	< 0.02	< 0.1
Lettuce 1.0 lbs ai/acre; 3.2 lbs ai/acre/year; ground application	**Short grass** (240 ppm)	240 ppm	768 ppm	< 0.04	< 0.1
	Long grass (110 ppm)	110 ppm	352 ppm	< 0.02	< 0.06
	Broadleaf plants/ small insects (135 ppm)	135 ppm	432 ppm	< 0.02	< 0.08
	Fruits/large insects/seeds (15 ppm)	15 ppm	48 ppm	< 0.002	< 0.01
Strawberry 1.0 lb ai/acre; 4.0 lbs ai/acre/year in California and 6.3 lbs ai/acre/year in all other states; aerial or ground application	**Short grass** (240 ppm)	240 ppm	1,512 ppm (960 ppm in CA)	< 0.04	< 0.3 (< 0.2 in CA)
	Long grass (110 ppm)	110 ppm	693 ppm (440 ppm in CA)	< 0.02	< 0.1
	Broadleaf plants/ small insects (135 ppm)	135 ppm	851 ppm (540 ppm in CA)	< 0.02	< 0.2
	Fruits/large insects/seeds (15 ppm)	15 ppm	95 ppm (60 ppm in CA)	< 0.003	< 0.02
Raspberry (black and red) 1.0 lb ai/acre; 4.2 lbs/acre/year; ground application	**Short grass** (240 ppm)	240 ppm	1,008 ppm	< 0.04	< 0.2
	Long grass (110 ppm)	110 ppm	462 ppm	< 0.02	< 0.1
	Broadleaf plants/ small insects (135 ppm)	135 ppm	567 ppm	< 0.02	< 0.1
	Fruits/large insects/seeds (15 ppm)	15 ppm	63 ppm	< 0.003	< 0.01

Estimated Environmental Concentrations (EEC) and Avian Acute Risk Quotients (RQ)
(based on EEC/the highest test concentration in the avian dietary LC50 studies, 5,620 ppm)

Use site; maximum single application rate; maximum seasonal application rate; and method of application	**Food items** (residue level following a 1 lb ai/acre application Fletcher, 1994)	**EEC** (1 application)	**EEC** (multiple applications with no degradation)	**Acute RQ** (single application)	**Acute RQ** (multiple applications)
Forest trees, ornamental and/or shade trees, and ornamental nonflowering plants 0.094 lbs ai/1000 sq ft (4.1 lbs ai/acre); 6.0 lbs ai/acre/year; ground application	**Short grass** (240 ppm)	984 ppm	1,440 ppm	< 0.2	< 0.3
	Long grass (110 ppm)	451 ppm	660 ppm	< 0.1	< 0.1
	Broadleaf plants/ small insects (135 ppm)	554 ppm	810 ppm	< 0.1	< 0.1
	Fruits/large insects/seeds (15 ppm)	62 ppm	90 ppm	< 0.01	< 0.2
Ornamental herbaceous plants and ornamental woody shrubs and vines 0.78 lbs ai/acre; 6.0 lbs ai/acre/year; aerial or ground application	**Short grass** (240 ppm)	188 ppm	1,440 ppm	< 0.03	< 0.3
	Long grass (110 ppm)	86 ppm	660 ppm	< 0.02	< 0.1
	Broadleaf plants/ small insects (135 ppm)	105 ppm	810 ppm	< 0.02	< 0.1
	Fruits/large insects/seeds (15 ppm)	12 ppm	90 ppm	< 0.002	< 0.02
Ornamental lawns and turf 5.7 lbs ai/acre; 6.0 lbs ai/acre/year; ground application	**Short grass** (240 ppm)	1,368 ppm	1,440 ppm	< 0.2	< 0.2
	Long grass (110 ppm)	627 ppm	660 ppm	< 0.1	< 0.1
	Broadleaf plants/ small insects (135 ppm)	770 ppm	810 ppm	< 0.1	< 0.1
	Fruits/large insects/seeds (15 ppm)	86 ppm	90 ppm	< 0.02	< 0.02

The highest test concentration (5,620 ppm) was used in the risk quotient calculations because LC50 values were not calculated in the studies. Risk quotient calculations, based on available application rate and method information provided in the table above, do not exceed acute high risk levels of concern (LOC's) except in the case of multiple banded applications to onions. Acute high risk LOCs are exceeded for grass

within the band following multiple applications and no degradation. Under these circumstances it is unlikely that vinclozolin applied to onions would pose a high acute risk to birds. Endangered species LOCs ($\geq$ 0.1) are exceeded for several use sites following single and multiple applications to grass with no degradation. As no dose related mortality was observed in any acute or subacute study, it can be assumed that dietary exposure at levels up to 5,620 ppm would not result in mortality in the field. Therefore, none of the presently registered uses would pose an acute risk to endangered or non-endangered birds.

(b) Chronic Risk to Birds

Maximum estimated residue levels for dietary food items following vinclozolin applications may be compared to the no-observed effect concentration (NOEC) in avian reproduction studies to assess chronic hazard. The maximum concentrations of vinclozolin residues on short grass following single and multiple applications and corresponding risk quotients are provided in the table below.

Avian Chronic Risk Quotients (RQ): EEC/NOEC (based on the NOEC of 50 ppm for bobwhite quail)								
Use site	**EEC** (ppm) (single application)		**EEC** (multiple applications, no degradation, ppm)		**Chronic RQ** (single application)		**Chronic RQ** (multiple applications, no degradation)	
	Broadleaf plants and insects	Short grass	Broadleaf plants and insects	Short grass	Broadleaf plants and insects	Short grass	Broadleaf plants and insects	Short grass
Apricot, cherry, nectarine, and peach	135	240	567	1,008	2.7	4.8	11	20
Chicory	1,175	2,088	N/A	N/A	24	42	N/A	N/A
Kiwi fruit	270	480	540	960	5.4	9.6	11	19
Onion	1,080 (within the band)	1,920 (within the band)	5,616 (within the band)	9,984 (within the band)	22	38	112	200
Lettuce	135	240	432	768	2.7	4.8	8.6	15
Strawberry	135	240	851 (540 in CA)	1,512 (960 in CA)	2.7	4.8	17 (11 in CA)	30 (19 in CA)
Raspberry	135	240	567	1,008	2.7	4.8	11	20
Forest trees, ornamental shade trees, and nonflowering plants	554	984	810	1,440	11	20	16	29
Ornamental herbaceous plants and woody shrubs and vines	105	188	810	1,440	2.1	3.8	16	29
Ornamental lawns and turf	770	1,368	810	1,440	15	27	16	29

The LOEL for bobwhite quail is 125 ppm where significantly reduced eggs laid, egg shell thickness, and proportion of 14 day old survivors of hatched chicks were observed. The NOEC for bobwhite quail is 50 ppm. The LOEL for mallard duck is 250 ppm where

significantly reduced hatchling success was observed. The NOEC for mallard duck is 125 ppm.

Risk quotients exceed the chronic high risk LOC (1.0) for all use sites for both single and multiple applications. Risk quotients (excluding onions) for single applications ranged from 2.1 to 42, and from 8.6 to 30 for multiple applications (chicory is excluded because it does not have multiple applications). Therefore, vinclozolin poses a chronic risk to birds.

In addition to concerns based on conventional measurement endpoints (e.g., reduced eggs laid) in avian reproduction studies, vinclozolin has been shown to cause antiandrogenic effects in laboratory rats. The potential for avian genital and reproductive tract malformations in adult male offspring and fertility in adult female offspring following exposure to vinclozolin has not been evaluated. It should be noted that mammalian hormone disruption may indicate the potential for hormone disruption in avian species. The implication of environmental hormone disruption, coupled with relatively large avian chronic LOC exceedances based on conventional avian reproduction tests, suggests high chronic risk to birds.

(c) Acute Risk to Mammals

Maximum estimated residue levels for dietary food items following vinclozolin applications may be compared to acute oral LD50 values for laboratory rats to assess risk. The following formula is used to calculate acute mammalian risk quotients (RQ):

$$\frac{\text{EEC} \times \text{proportion of body weight a mammal consumes per day}}{\text{LD50 value}} = \text{RQ}$$

The maximum concentration of vinclozolin residues on selected mammalian food items following vinclozolin applications on two registered use sites with the highest use rates (onions and chicory) and the corresponding mammalian acute risk quotients are provided in the table below.

Estimated Environmental Concentrations (EEC) and Mammalian Acute Risk Quotients (RQ) (based on the LD50 value for laboratory rats, > 10,000 mg/kg)

Herbivores/Insectivores

Use site, application rate and method	Body weight (g)	% of body weight consumed	EEC (short grass)	EEC (broadleaf plants/ small insects)	EEC (fruits/ large insects)	RQ (short grass)	RQ (broad leaves/ small insects)	RQ (fruits/ large insects)
Onions 5.2 lbs ai/A/y 3" band over the row	15	95	9,984 ppm	5,616 ppm	624 ppm	< 1.9	< 1.1	< 0.1
	35	66	9,984 ppm	5,616 ppm	624 ppm	< 1.3	< 0.7	< 0.1
	1,000	46	9,984 ppm	5,616 ppm	624 ppm	< 0.9	< 0.5	< 0.1
Chicory 8.7 lbs ai/A/y broadcast (ground)	15	95	2,088 ppm	1,175 ppm	131 ppm	< 0.4	< 0.2	< 0.2
	35	66	2,088 ppm	1,175 ppm	131 ppm	< 0.3	< 0.2	< 0.02
	1,000	46	2,088 ppm	1,175 ppm	131 ppm	< 0.2	< 0.1	< 0.01

Estimated Environmental Concentrations (EEC) and Mammalian Acute Risk Quotients (RQ) (based on the LD50 value for laboratory rats, > 10,000 mg/kg)				
Granivores				
Use site, application rate and method	**body weight (g)**	**% of body weight consumed**	**EEC (seeds)**	**RQ (seeds)**
Onions **5.2 lbs ai/acre/year** 3" band over the row	15	21	624 ppm	< 0.03
	35	15	624 ppm	< 0.02
	1,000	3	624 ppm	< 0.003
Chicory **8.7 lbs ai/acre/year** broadcast (ground)	15	21	131 ppm	< 0.006
	35	15	131 ppm	< 0.004
	1,000	3	131 ppm	< 0.002

The highest test concentration (10,000 mg/kg) was used in the risk quotient calculations because LD50 values were not calculated in the studies. Risk quotients, based on available application rate and method information provided in the table above, do not exceed mammalian high acute risk LOC's except in the case of multiple banded applications to onions (with no degradation). Under these circumstances it is unlikely that vinclozolin applied to onions would pose a high acute risk to mammals. Endangered species LOCs ($\geq$ 0.1) are exceeded for several use sites following multiple applications with no degradation. As no dose related mortality was observed in any acute study, it can be assumed that dietary exposures resulting in an equivalent of 10,000 mg/kg would not result in mortality in the field. Therefore, none of the present registered uses would pose an acute risk to endangered or non-endangered mammals.

(d) Chronic Risk to Mammals

Maximum estimated residue levels for dietary food items following vinclozolin applications may be compared to the no-observed effect concentration (NOEC) in mammalian chronic toxicity studies to assess chronic risk. The maximum concentrations of vinclozolin residues on short grass following single and multiple applications and corresponding risk quotients are provided in the table below.

Mammalian reproduction studies required by the Agency's Health Effects Division (HED) are used to determine chronic toxicity to mammals. In a two generation rat study, chronic effects to laboratory rats include epididymal weight reduction at the 300 ppm test concentration. Adult male offspring sired no offspring at 1000 and 3000 ppm. Genital and reproductive tract malformations (including hypospadia) were observed at 1,000 ppm. Fertility in adult female offspring may have been reduced at 3,000 ppm.

In an additional study, subtle, reversible reductions in anal-genital distance were observed in males at 50 mg/kg. Other effects observed included: retained nipples, and reduction in ventral prostrate and seminal vesicle gland weights in male rat offspring at 12, 25, 50 and 100 mg/kg/day.

Although effects were observed below 300 ppm, EEB does not consider them to be significant. Therefore, the NOEC to be used is 300 ppm.

Mammalian Chronic Risk Quotients (RQ): EEC/NOEC (based on the NOEC of 300 ppm for laboratory rat)								
Use site	EEC (ppm) (single application)		EEC (multiple applications, no degradation, ppm)		Chronic RQ (single application)		Chronic RQ (multiple applications, no degradation)	
	Broadleaf plants and insects	Short grass	Broadleaf plants and insects	Short grass	Broadleaf plants and insects	Short grass	Broadleaf plants and insects	Short grass
Apricot, cherry, nectarine, and peach	135	240	567	1,008	0.5	0.8	1.8	3.3
Chicory	1,175	2,088	N/A	N/A	4.0	7.0	N/A	N/A
Kiwi fruit	270	480	540	960	0.9	1.6	1.8	3.1
Onion	1,080 (within the band)	1,920 (within the band)	5,616 (within the band)	9,984 (within the band)	3.7	6.3	18	33
Lettuce	135	240	432	768	0.5	0.8	1.4	2.5
Strawberry	135	240	851 (540 in CA)	1,512 (960 in CA)	0.5	0.8	2.8 (1.8 in CA)	5.0 (3.2 in CA)
Raspberry	135	240	567	1,008	0.5	0.8	1.8	3.3
Forest trees, ornamental shade trees, and nonflowering plants	554	984	810	1,440	1.8	3.3	2.7	4.8
Ornamental herbaceous plants and woody shrubs and vines	105	188	810	1,440	0.4	0.6	2.7	4.8
Ornamental lawns and turf	770	1,368	810	1,440	2.5	4.5	3.2	4.8

Risk quotients exceed the chronic high risk LOC (1.0) for several use sites following a single application and for all use sites following multiple applications. Risk quotients (excluding onions) for single applications ranged

from 0.4 to 7.0, and from 1.4 to 5.0 for multiple applications (chicory is excluded because it does not have multiple applications). Therefore, vinclozolin poses a chronic risk to mammals.

(e) Acute Risk to Insects

Data indicate that vinclozolin may be characterized as practically nontoxic to honey bees with an LD50 value of > 100 ug/bee. Therefore, vinclozolin does not pose a high risk to honey bees.

(2) Exposure and Risk to Aquatic Organisms

(a) Acute Risk to Freshwater Fish and Invertebrates

Estimated Environmental Concentrations: EFED calculated generic EEC levels for vinclozolin based on runoff from a 10 hectare field to a 1 hectare x 2 meter deep water body. These generic EEC's (GEEC's) take into account degradation in the field prior to a rain event. The following environmental fate parameters were used in the model: Soil KOC 396, Solubility 2.6 ppm, Aerobic soil metabolism 53 days, Hydrolysis (pH 7) 1.3 days, and Photolysis in water 27.2 days. No aquatic metabolism data were available, therefore, the default value of 0 was used. EECs were calculated for single application, and multiple applications 7 days apart. These EECs, along with the calculated risk quotients are provided in the table below.

Estimated Environmental Concentrations (EEC) based on GENEEC and Acute Risk Quotients for Freshwater organisms based on an LC50 of 2.8 ppm for freshwater fish (rainbow trout) and an EC50 of 4.0 ppm for aquatic invertebrate (*Daphnia magna*)

Use Site, application rate and method		Initial EEC (ppb)	4-day EEC (ppb)	21-day EEC (ppb)	56-day EEC (ppb)	Acute RQ (Initial EEC/LC50)	
						Rainbow trout	*Daphnia magna*
Apricot, Cherry, Nectarine, Peach	1 lb ai/acre (ground)	22.4	11.9	2.6	1.0	0.01	0.01
	4.2 lb ai/acre/ year (aerial)	78.7	42.0	9.1	3.4	0.03	0.02
Chicory	8.7 lbs ai/acre (ground)	195.1	103.5	22.3	8.4	0.05	0.04
Kiwi fruit	2.0 lbs ai/acre (ground)	44.9	23.8	5.1	1.9	0.01	0.01
	4.0 lb ai/acre/ year (ground)	88.3	46.9	10.1	3.8	0.03	0.02
Onion (dry bulb type)	1.0 lb ai/acre (ground)	22.4	11.9	2.6	1.0	0.01	0.01
	5.2 lb ai/acre/ year (ground)	96.5	51.2	11.0	4.1	0.03	0.03
Lettuce	1.0 lb ai/acre (ground)	22.4	11.9	2.6	1.0	0.01	0.01
	3.2 lb ai/acre/ year (ground)	63.2	33.5	7.2	2.7	0.02	0.02
Strawberry	1.0 lb ai/acre (ground)	22.4	11.9	2.6	1.0	0.01	0.01
	6.3 lb ai/acre/ year (aerial)	107.9	57.5	12.4	4.6	0.03	0.03
Raspberry (black and red)	1.0 lb ai/acre (ground)	22.4	11.9	2.6	1.0	0.01	0.01
	4.2 lb ai/acre/ year (ground)	80.6	42.8	9.2	3.5	0.03	0.02
Forest trees, ornamental and/or shade trees, and ornamental nonflowering plants	4.1 lb ai/acre (ground)	89.7	47.6	10.2	3.8	0.03	0.02
	6.0 lb ai/acre/ year (ground)	132.4	70.3	15.1	5.7	0.04	0.03
Ornamental herbaceous plants and ornamental woody shrubs and vines	0.78 lb ai/acre (ground)	17.5	9.3	2.0	0.8	0.01	0.01
	6.0 lb ai/acre/ year (aerial)	94.0	50.1	10.8	4.0	0.03	0.02
Ornamental lawns and turf	6.0 lb ai/acre/ year (ground)	134.6	71.4	15.4	5.8	0.04	0.03

Acute LOCs have not been exceeded for freshwater fish or invertebrates. Therefore, vinclozolin does not pose an acute risk to freshwater fish and aquatic invertebrates.

Chronic toxicity data are not available for freshwater organisms, therefore a chronic risk assessment cannot be done. Once the required studies are submitted, the chronic assessment will be conducted.

(b) Acute and Chronic Risk to Estuarine and Marine Organisms

No acute or chronic toxicity data are available for estuarine and marine organisms. Once the required studies are submitted, the risk assessment will be conducted.

(3) Exposure and Risk to Nontarget Plants

(a) Risk to Aquatic Nontarget Plants

Although the available Tier I data did not fulfill the data requirements, the studies did provide data for a preliminary risk assessment. The table below provides EEC's and risk quotients for aquatic plants.

Estimated Environmental Concentrations (EEC) based on GENEEC and Risk Quotients for Aquatic Plants (based on an effect concentration of 1.0 ppm for aquatic plants			
Use site		**Initial EEC**	**RQ (EEC/ Effect Level)**
Apricot, Cherry, Nectarine, Peach	1 lb ai/acre (ground)	22.4	< 0.02
	4.2 lb ai/acre/ year (aerial)	78.7	< 0.08
Chicory	8.7 lbs ai/acre (ground)	195.1	< 0.2
Kiwi fruit	2.0 lbs ai/acre (ground)	44.9	< 0.04
	4.0 lb ai/acre/ year (ground)	88.3	< 0.09
Onion (dry bulb type)	1.0 lb ai/acre (ground)	22.4	< 0.02
	5.2 lb ai/acre/ year (ground)	96.5	< 0.1
Lettuce	1.0 lb ai/acre (ground)	22.4	< 0.02
	3.2 lb ai/acre/ year (ground)	63.2	< 0.07
Strawberry	1.0 lb ai/acre (ground)	22.4	< 0.02
	6.3 lb ai/acre/ year (aerial)	107.9	< 0.1
Raspberry (black and red)	1.0 lb ai/acre (ground)	22.4	< 0.02
	4.2 lb ai/acre/ year (ground)	80.6	< 0.07
Forest trees, ornamental and/or shade trees, and ornamental nonflowering plants	4.1 lb ai/acre (ground)	89.7	< 0.08
	6.0 lb ai/acre/ year (ground)	132.4	< 0.1
Ornamental herbaceous plants and ornamental woody shrubs and vines	0.78 lb ai/acre (ground)	17.5	< 0.01
	6.0 lb ai/acre/ year (aerial)	94.0	< 0.08
Ornamental lawns and turf	6.0 lb ai/acre/ year (ground)	134.6	< 0.1

Risk quotients do not exceed the LOC for aquatic plants (1.0). Therefore, based on the above preliminary risk assessment, vinclozolin does not pose an acute risk to aquatic plants. However, the concentration in the Tier I tests was not high enough to evaluate effects at most application rates. Tier I plant testing should be repeated.

(4) Endangered Species

Avian and mammalian chronic LOCs or endangered species have been exceeded for all vinclozolin use sites. The Endangered Species Protection Program is expected to become final in the future. Limitations in the use of vinclozolin may be required to protect endangered species, but these limitations have not been defined and may be formulation specific. EPA anticipates that a consultation with the Fish and Wildlife Service may be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

(5) Risk Characterization Summary

The major concern with vinclozolin is the chronic risk to mammals and birds. Toxicity studies have demonstrated the potential to cause reproductive and developmental effects. A chronic risk assessment for aquatic organisms can not be completed because chronic data are lacking.